

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, et al.)
PRETERM INFANT NUTRITION) MDL No. 3026
PRODUCTS LIABILITY LITIGATION)
) Master Docket No. 22 C 71
)
) Judge Rebecca R. Pallmeyer
)
<hr/>	
TYRONZA RODDY, Individually, and as) COMPLAINT AND JURY DEMAND
next of friend of J. M. R., a minor,)
) Civil Action No. _____
Plaintiffs,)
) Designated Home State: <u>Arkansas</u>
)
v.)
)
ABBOTT LABORATORIES, INC.,)
ABBOTT LABORATORIES,)
MEAD JOHNSON & COMPANY, LLC,)
and MEAD JOHNSON NUTRITION)
COMPANY,)
)
)
Defendants.)

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

COME NOW, Plaintiff, TYRONZA RODDY, Individually, and as next of friend of J. M. R., a minor, by and through the undersigned counsel, sues Defendants, ABBOTT LABORATORIES, INC., ABBOTT LABORATORIES, MEAD JOHNSON & COMPANY, LLC, and MEAD JOHNSON NUTRITION COMPANY, and in support thereof state as follows:

INTRODUCTION

1. This action arises out of the catastrophic and preventable injuries of a

newborn baby who suffers from a horrific and deadly disease caused and/or substantially contributed to by cow's-milk-based infant formula and/or fortifier. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC may lead to surgery, developmental injuries, and including death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow's milk-based formula or fortifier products.

2. The companies who manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, J. M. R., a minor (hereinafter "JMR" or collectively as "Plaintiffs"), who was premature at birth, was fed these cow's milk-based products, developed NEC, and had to undergo treatment, and sustained substantial life-altering injuries thereafter.

3. Plaintiff, TYRONZA RODDY (hereinafter "Mother" or collectively as "Plaintiffs"), Individually, and as next of friend to JMR, brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendants' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendants' Cow's milk-based Products (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively

“Cow’s milk-based Products”).

JURISDICTION AND VENUE

4. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332 because there is complete diversity of the Plaintiffs and the Defendants and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

5. Under MDL 3026 Case Management Order No. 1, the Court has personal jurisdiction over Defendants because the Eastern District of Arkansas would have personal jurisdiction over Defendants. Defendants transacts business in the Eastern District of Arkansas and are corporations doing business within the Eastern District of Arkansas. Defendants know that its cow-milk based products are and were sold throughout the State of Arkansas. Defendants also maintain sufficient contacts with the State of Arkansas that the Eastern District of Arkansas’ exercise of personal jurisdiction over it does not offend traditional notions of fair play and substantial justice. Specific to this case, Defendants engaged in the business of developing, manufacturing, testing, packaging, marketing, distributing, and labeling pesticides containing paraquat in the State of Arkansas, thus making a lawsuit regarding paraquat filed in the State of Arkansas foreseeable. Defendants purposefully availed itself of the privilege of conducting activities within the Eastern District of Arkansas, thus invoking the benefits and protections of its laws.

6. Venue is proper in the Northern District of Illinois under MDL 3026 Case Management Order No. 1, as this case would be subject to transfer to MDL 3026.

[See Doc. No. 34].

7. If not for Case Management Order No. 1, venue would be proper in the Eastern District of Arkansas under 28 U.S.C. § 1391(b) because Defendants conduct business in that District, are subject to jurisdiction in that District, and have sold, marketed, and or distributed paraquat within that District at all times relevant to this suit; thus, a substantial part of the acts or occurrences giving rise to this suit occurred within the Southern District of Arkansas.

PLAINTIFFS

8. JMR was born prematurely at University of Arkansas for Medical Sciences in Little Rock, Arkansas on June 13, 2006. Upon information and belief, JMR developed NEC after being fed 22-calorie Preemie Enfamil, 24-calorie Premature Enfamil with thickit, Similac Neosure, and Pediasure; Defendants' Cow's milk-based Products while in the NICU at University of Arkansas for Medical Sciences in Little Rock, Arkansas.

9. Plaintiff, JMR is a resident a citizen of the State of Arkansas and resides with his mother and step-father in Newport, Jackson County, Arkansas.

10. Plaintiff, TYRONZA RODDY, the mother of JMR is a citizen of the State of Arkansas, and reside in Newport, Jackson County, Arkansas.

DEFENDANTS

11. Defendant, ABBOTT LABORATORIES, INC. ("Abbott Labs," "Abbott Defendants," or collectively as "Defendants") was at all times material hereto and is now a corporation duly organized, and existing under the laws of the State of

Delaware, with its principal place of business and headquarters located at 100 Abbott Park Road, Abbott Park, IL 60064. **Defendant may be served via its registered agent: CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604.**

12. Defendant, ABBOTT LABORATORIES, (“Abbott,” “Abbott Defendants,” or collectively as “Defendants”) was at all times material hereto and is now a corporation duly organized, and existing under the laws of the State of Illinois, with its principal place of business and headquarters located at 100 Abbott Park Road, Abbott Park, IL 60064. **Defendant may be served via its registered agent: CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604.**

13. Abbott Defendants manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty (50) states, including the State of Arkansas, and sells premature infant formula products including: Similac Sensitive, Similac Neosure, Pediasure, and Similac Special Care Advance 20.

14. Defendant, MEAD JOHNSON & COMPANY, LLC (“Mead,” “Mead Defendants,” or collectively as “Defendants”) was at all times material hereto and is now a corporation duly organized, and existing under the laws of the State of Delaware, with its principal place of business and headquarters located at 2400 W. Lloyd Expressway, Evansville, IN 47721. **Defendant may be served via its registered agent: Illinois Corporation Service Company, 801 Adlai Stevenson Drive, Springfield, IL 62703.**

15. Defendant, MEAD JOHNSON NUTRITION COMPANY (“Mead Nutrition” or collectively as “Defendants”) was at all times material hereto and is now a corporation duly organized, and existing under the laws of the State of Delaware, with its principal place of business and headquarters located at 225 N. Canal Street, 25th Floor, Chicago, IL 60606. **Defendant may be served via its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.**

16. Mead manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty (50) states, including the State of Arkansas, and sells premature infant formula products including; Preemie Enfamil, Premature Enfamil, Enfamil Human Milk Fortifier and Enfacare Powder.

GENERAL ALLEGATION

17. JMR was born prematurely with a low birth weight of 2 pounds and 11 ounces, and was the product of an approximate 24-week pregnancy.

18. JMR developed Necrotizing Enterocolitis while in the NICU and had to undergo imaging and treatment due to the condition.

19. The development of Necrotizing Enterocolitis has caused other developmental injuries as JMR grows older.

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

20. According to the World Health Organization (“WHO”), babies born prematurely, or “preterm,” are defined as being born alive before 37 weeks of

pregnancy are completed; as JMR was born prematurely at approximately 24 weeks. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

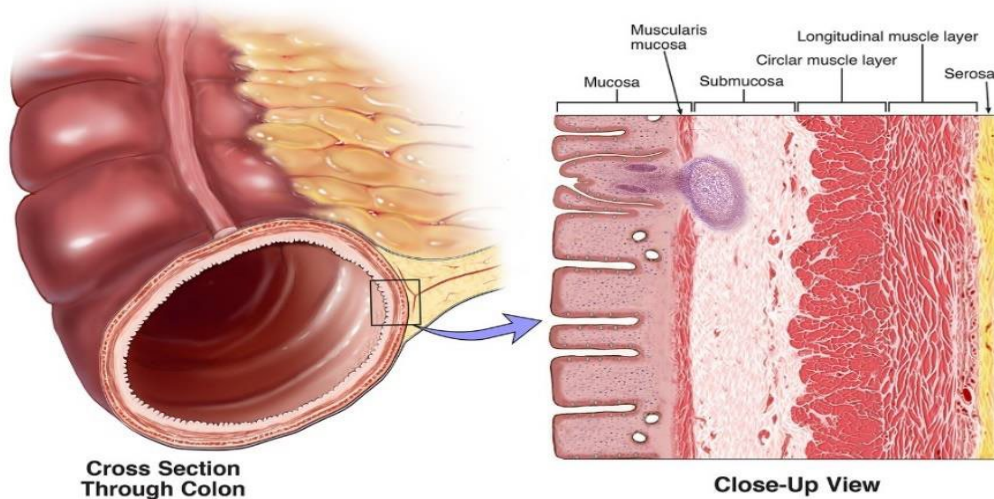
21. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

22. Science and research have advanced in recent years confirming strong links between cow's milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products; however, the manufacturers of the Cow's milk-based Products continue to promote and sell the Cow's milk-based Product versions.

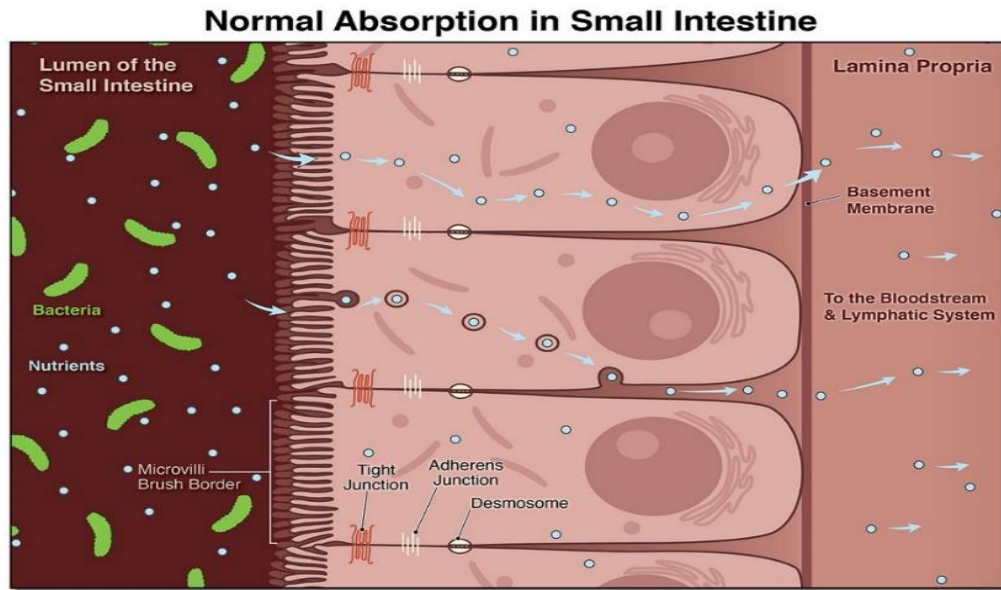
23. To illustrate the danger posed to preterm infants, this is a diagram of the normal layers of the baby's intestinal wall¹:

¹ All of the medical illustrations are provided to assist the Court in understanding this devastating disease and are subject to a copyright by MediVisuals, Inc. As such, they cannot be reproduced, reprinted, or used without permission of the copyright holder.

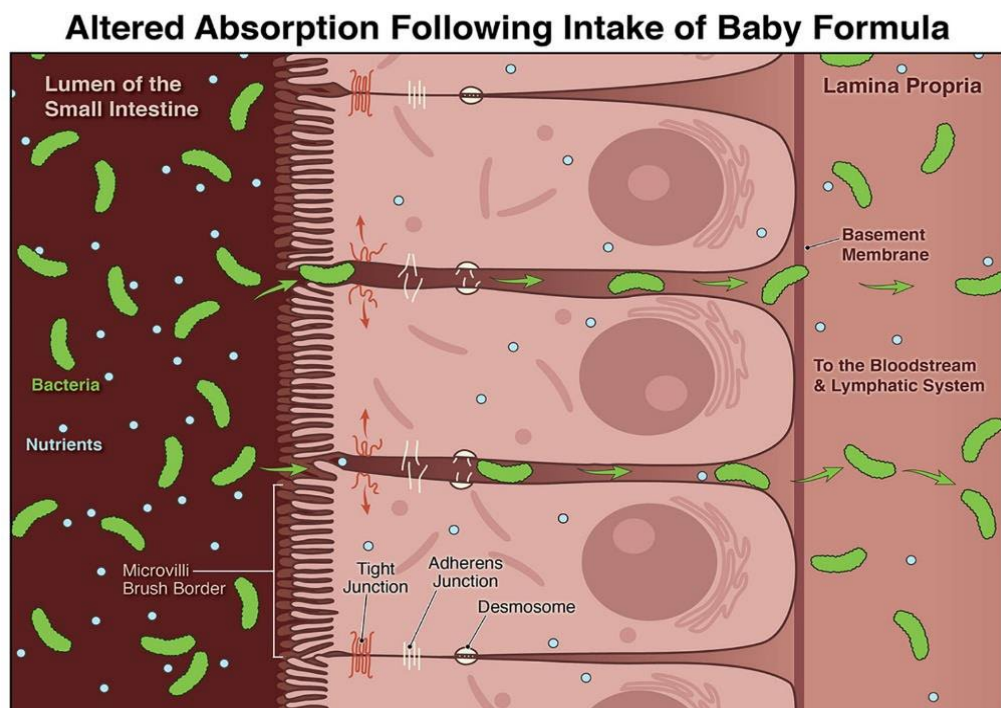
Layers of the Intestinal Wall



24. Normal absorption in the small intestine looks like the diagram below. The cells lining the lumen of the intestines have microvilli that magnify the surface area available for uptake. Nutrients, which are color-coded in light blue, are absorbed by these cells, then transported through the cells, and released where they are then transported to the rest of the body through the bloodstream and lymphatic system. The cells keep out the bacteria and toxins that are present in the intestines which would be harmful if absorbed into the other tissues of the body. The tight junctions between each cell play a major role in preventing the bacteria and toxins from entering the body.



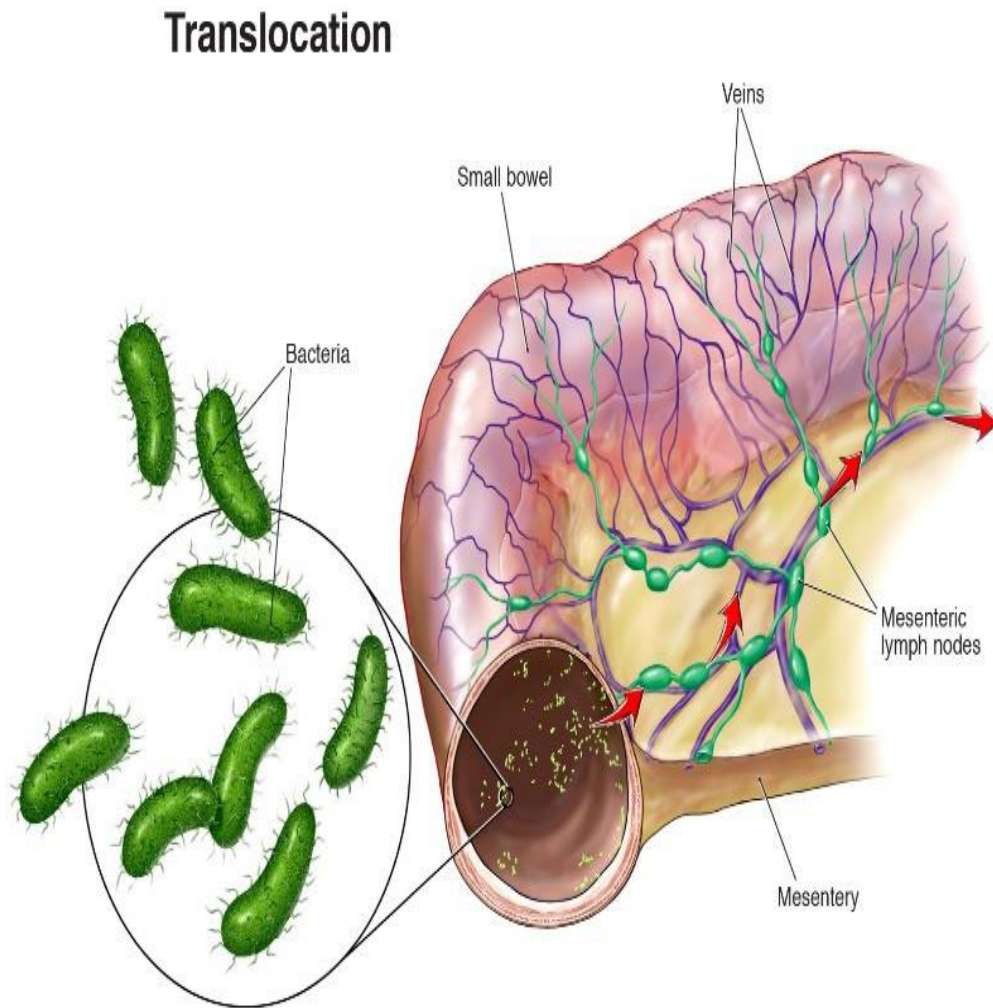
25. The diagram below shows how the absorption is significantly altered following the intake of Cow's milk-based Products:

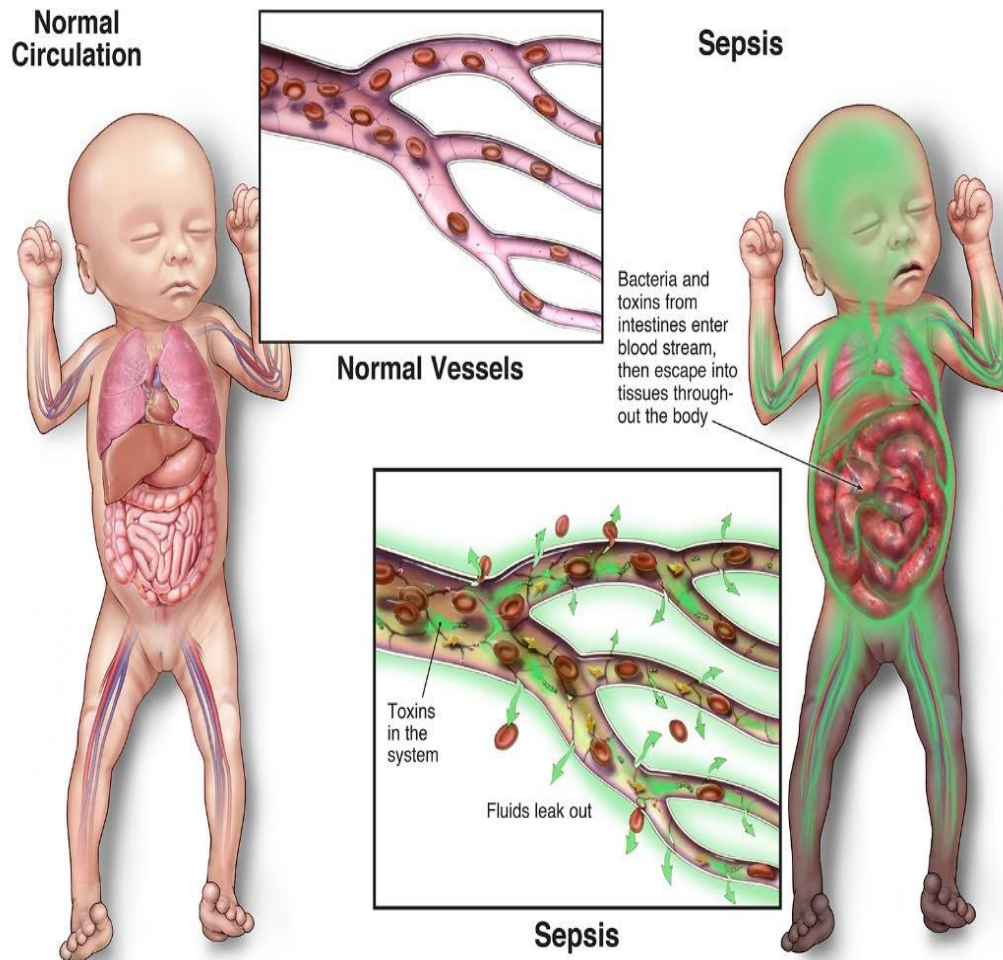


Specifically, this figure demonstrates what the breakdown of the tight junctions looks like after a preterm baby ingests the Cow's milk-based Products. As a result, the

harmful bacteria and toxins are able to enter the baby's bloodstream and lymphatics, which induces an inflammatory response (not pictured) in the baby's intestinal walls.

26. The figure to the right demonstrates the intestinal veins and lymphatics that transport the harmful bacteria and toxins that have entered the baby's intestinal wall following the ingestion of the Cow's milk-based Products.

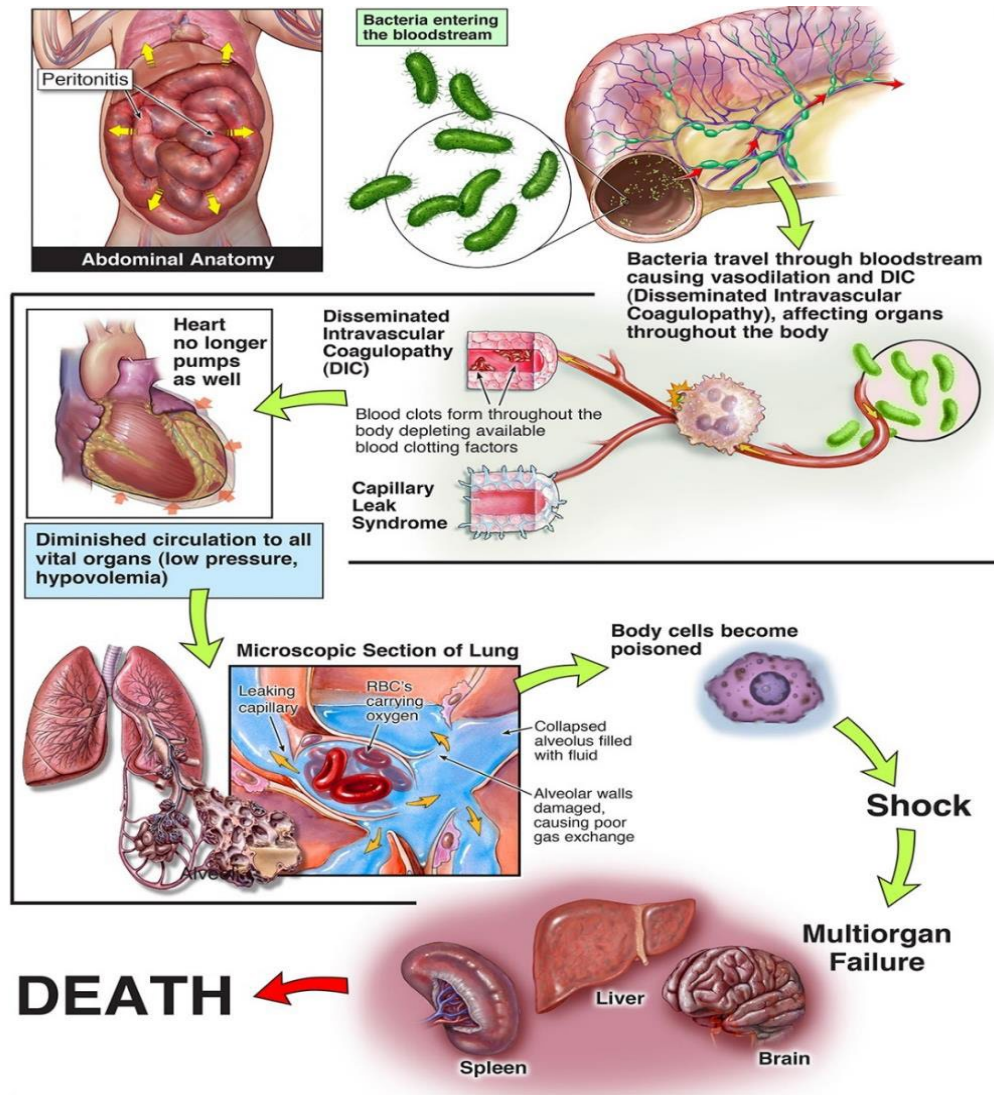




27. The image on the above is a simplified view of the major organs of the baby's chest and abdomen, as well as her circulatory system. The box at the top shows a magnified view of the normal functioning of small blood vessels and capillaries of the tissues throughout the body. As shown, tight intercellular junctions lining the capillaries prevent plasma from escaping into the surrounding tissues. By contrast, the baby depicted to the right is in distress, as is illustrated by her capillary bed where bacteria and toxins (shown in green) were transported from the intestines and spread to the rest of the body. These toxins further breakdown and weaken the tight,

intercellular junctions, and as a result, bacteria, toxins, and plasma escape into the surrounding interstitial spaces resulting in a condition known as “third-spacing,” and sepsis.

28. This harmful process is further illustrated in the series of images below. This process all begins with the administration of Cow’s milk-based Products and as shown in the illustration, can lead to sepsis, multi-system organ failure, surgery to remove necrosed intestine, developmental injuries in later life, including death.



29. This chart illustrates many of the classic signs and symptoms of NEC experienced by these vulnerable preterm babies after ingesting Cow's milk-based Products

Classic Signs and Symptoms of NEC		Yes	No
• Irritability (crying)	<input type="checkbox"/>	<input type="checkbox"/>	
• Pain	<input type="checkbox"/>	<input type="checkbox"/>	
• Abdominal distention	<input type="checkbox"/>	<input type="checkbox"/>	
• Hyperthermia	<input type="checkbox"/>	<input type="checkbox"/>	
• Tachycardia	<input type="checkbox"/>	<input type="checkbox"/>	
• Decreased bowel sounds	<input type="checkbox"/>	<input type="checkbox"/>	
• Lethargy	<input type="checkbox"/>	<input type="checkbox"/>	
• Reduced urine output	<input type="checkbox"/>	<input type="checkbox"/>	
• Shock	<input type="checkbox"/>	<input type="checkbox"/>	
• Free air in abdomen	<input type="checkbox"/>	<input type="checkbox"/>	
• Elevated white blood count	<input type="checkbox"/>	<input type="checkbox"/>	
• Tenderness	<input type="checkbox"/>	<input type="checkbox"/>	
• Portal venous gas	<input type="checkbox"/>	<input type="checkbox"/>	
• Greenish discoloration	<input type="checkbox"/>	<input type="checkbox"/>	
• Worsening or persistent thrombocytopenia	<input type="checkbox"/>	<input type="checkbox"/>	
• Completely gasless abdomen	<input type="checkbox"/>	<input type="checkbox"/>	
• Repeated feeding intolerance	<input type="checkbox"/>	<input type="checkbox"/>	
• Intestinal strictures	<input type="checkbox"/>	<input type="checkbox"/>	
• Passage of meconium through patent processus vaginalitis	<input type="checkbox"/>	<input type="checkbox"/>	
• Fixed and dilated loop on serial abdominal radiographs	<input type="checkbox"/>	<input type="checkbox"/>	

30. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was **six to ten times more** common in exclusively formula-fed babies than in those fed breast milk alone and **three times more common** than in those who received formula plus breast milk. Babies born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast milk, but it was **20 times more common** in those fed formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990)

(emphasis added).

31. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were **90% less likely** to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, *et al*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

32. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, **formula feeding is associated with higher rates** of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added). This same report stated that premature infants who are not breastfed are **138% more likely** to develop NEC. *Id.*, Table 1, p.2.

33. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's milk-based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable

...pasteurized donor milk should be used." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e841 (2012).

34. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and weight and head circumference gain. The authors concluded that "this study provides data showing that **infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet**." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤ 1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's milk-based Products, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendants.

35. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a **significantly higher rate** of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU (Newborn Intensive Care Unit). E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

36. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant**

morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al.*, *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease.**" *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

37. In yet another study published in 2014 it was reported that an exclusive human milk diet, devoid of Cow's milk-based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286

(2014).

38. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an **exclusive human milk diet is associated with “significant benefits”** for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, “it appears that there were **no feeding-related adverse outcomes.**” Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

39. A publication by the American Society for Nutrition, in 2017, noted that human milk has “been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC.” The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow’s milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an **exclusive human milk diet resulted in a much lower incidence of NEC**. While the study noted that cow’s milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **cow’s milk-based products significantly increase the risk of NEC and death**. The study also noted the

“exponential” health care costs associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is \$180,000 to \$198,000 per infant and nearly doubles to \$313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

40. The WHO and United Nation’s International Children’s Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, **“In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement.”** Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

41. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly (“WHA”), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: **“There should be no advertising or other form of promotion to the general public [of breast milk substitutes].”** (emphasis

added). In Article 5.2, the Code states that “manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.” In addition, the Code expressly prohibits, “point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales...” See Int’l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

42. The World Health Organization’s 2018 Status Report on this issue noted that “despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended.” The Status Report states that “**a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes**,” noting that in 2014, the global sales of breast-milk substitutes amounted to **US \$44.8 billion** and “is expected to rise to **US \$70.6 billion** by 2019.” *Marketing of Breast-milk Substitutes: Nat’l Implementation of the Int’l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added).

43. Recognizing a shift in the medical community towards an exclusive human-based diet for preterm infants, the Defendants began heavily promoting “human milk fortifiers,” a name which misleadingly suggests that the product is derived from human milk, instead of being derived from cow’s milk.

44. The Defendants have separately designed competing, systematic, powerful, and misleading marketing campaigns to persuade physicians and parents

to believe that: (1) Cow's milk-based Products are safe; (2) Cow's milk-based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's milk-based Products a first choice. Similarly, the Defendants market their products for preterm infants as necessary for growth, and are perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's milk-based Products and failing to warn of the deadly disease of NEC and risk of death.

45. Thus, despite the existence of alternative and safe human milk-based formulas and fortifiers, these Defendants continue to market and/or sell the Cow's milk-based Products under the guise of being a safe product for their newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like JMR.

The Inadequate Warnings

46. Defendants promote the use of their preterm infant Cow's milk-based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

47. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's milk-based Products, including the significant risk of NEC, developmental injuries in later life, and death; Defendants did not warn parents or medical providers of the risk of NEC, nor did Defendants provide any instructions or guidance on how to properly use its Cow's milk-based Products so as to lower the risk or avoid NEC or other serious injuries, including death.

48. In fact, neither of the Defendants provide any warning in their labeling,

websites, or marketing that discusses the risk of NEC, serious bodily injury, including death with use of their Cow's milk-based Products with preterm infants.

49. The warning on Similac Human Milk Fortifier, an Abbott Cow's milk-based Product specifically marketed for use with preterm-infants states:

Precautions

- Add only to human milk—do not add water;
- This product is nutritionally incomplete by itself and is designed to be added to human breast milk;
- Additional iron may be necessary;
- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk;
- Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk; and
- Not intended for feeding low-birth-weight infants after the reach a weight of 3600 g (approximately 8 lb) or as directed by a physician

Preparation and Use

- Follow directions as specified on carton. Improper dilution may be harmful.

50. The warning on Enfamil Human Milk Fortifier, a Mead Johnson Cow's milk-based Product specifically marketed for use with preterm-infants states:

WARNING: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although this powder is formulated for premature infants, nutritional powders are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

Follow hospital rules or your baby's doctor's instructions for the safe

handling of human milk.

To aid mixing, agitate the human milk well. Pour the desired amount into a sterile container and warm to feeding temperature.

1. Remove vials from foil pouch and separate number of vials needed.
2. Store remaining vials in foil pouch at room temperature. Once pouch has been opened, vials must be used within 24 hours.
3. Shake vigorously to mix contents. Firmly hold vial UPRIGHT by bottom tab and slowly twist top off completely. Add fortifier to breast milk.

Some liquid may remain in cap and vial; disregard [sic] this liquid. Discard opened vial and cap promptly. Do not use product that has unusual characteristics.

1. **Failure to follow these instructions could result in severe harm. Once prepared, fortified breast milk can spoil quickly.** Either feed fortified breast milk immediately or cover and store in refrigerator at 35-40°F (2-4°C) for no longer than 24 hours. Agitate before each use.
2. **For bottle feeding:** Pour only the amount of fortified breast milk to be fed into a feeding container and feed immediately. Do not use fortified breast milk if it is unrefrigerated for more than a total of 2 hours. After feeding begins, use fortified breast milk within one hour or discard.
3. **For tube feeding:** Once fortified breast milk is prepared, it can remain at room temperature for no longer than a total of 4 hours.

Warning: Do not use a microwave oven to warm the fortified human milk. Serious burns may result.

Storage: Store unopen pouches in carton at room temperature. Avoid excessive heat. Do not freeze.

Warning: Not for parental (I.V.) use. Fortifier is designed to be mixed with breast milk; do not administer directly.

51. Thus, Defendants do not warn the users, the parents, or the medical providers and staff that these Cow's milk-based Products can cause NEC, other serious injuries, including death, nor do they provide any guidance on how to avoid or reduce the risks of NEC, other serious injuries, including death while using their products.

JMR and the Dangerous, Defective Products

52. JMR was born at University of Arkansas for Medical Sciences in Little Rock, Arkansas on June 13, 2006. JMR was born preterm at approximately 24 weeks gestation age with a low birth weight of 2 pounds 11 ounces.

53. After he was born, JMR was placed on a ventilator in the intensive care unit at University of Arkansas for Medical Sciences in Little Rock, Arkansas.

54. Following his birth, his mother was unsuccessful in pumping her own breast milk for her baby's nutrition for an extended period of time.

55. JMR was fed 22-calorie Preemie Enfamil and 24-calorie Premature Enfamil with thickit, Mead Defendants' Cow's milk-based Products on or about June 23, 2006 until he was discharged and transferred to Arkansas Children's Hospital on September 15, 2006.

56. JMR was fed Similac Neosure and Pediasure, Abbott Defendants' Cow's milk-based Products starting approximately after September 15, 2006.

57. On or about July 13, 2006, JMR underwent various AP Chest exams that provided the possibility of JMR having Necrotizing Enterocolitis.

58. Following the feeding of Defendants' Cow's milk-based Products, JMR has had continuing developmental injuries that are being treated to this day.

59. At the time of JMR's birth, his mother was unaware of the fact that the Defendants' cow's milk-based products he was fed caused or substantially contributed to his development of NEC and continuing developmental injuries.

COUNTS

COUNT I: STRICT LIABILITY AS TO ABBOTT DEFENDANTS DESIGN

60. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

61. At all times material to this action, Abbott Defendants were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's milk-based Products, which are defectively designed and/or unreasonably dangerous to consumers, including JMR.

62. Abbott Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

63. At all times material to this action, the Cow's milk-based Products manufactured, distributed and/or sold by Abbott Defendants, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

64. Abbott Defendants specifically marketed and created its Cow's milk-based Products for use as nutrition and nutritional supplements for preterm infants,

like JMR.

65. Abbott Defendants' Cow's milk-based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

66. Prior to August 2012, Abbott Defendants were aware or should have been aware that its Cow's milk-based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

67. Abbott Defendants knew or should have known that the use of its Cow's milk-based Products with preterm infants was unreasonably dangerous in that its Cow's milk-based Products significantly increased the risk of NEC, other serious injuries, including death.

68. Furthermore, scientific data and well-researched studies have concluded that the Cow's milk-based Products of the Abbott Defendants carried unreasonable risks of NEC including death and later developmental injuries, which far outweighed the products' benefits for preterm infants like JMR.

69. Despite the foregoing, the Defendants continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

70. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

- a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's milk-based Products as nutrition or nutritional

supplements in preterm infants significantly increased the risk of NEC, serious injuries, including death;

- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as JMR to risks of serious bodily injury, including death;
- c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;
- d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;
- e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;
- f. Abbott Defendants failed to adopt an adequate or sufficient quality control program; and/or
- g. Abbott Defendants failed to inspect or test their products with sufficient care.

71. As a direct and proximate cause of the Cow's milk-based Products' unreasonable dangerous condition, JMR suffered serious bodily injury, which resulted in his serious injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories, Inc. and Abbot Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT II: NEGLIGENCE AS TO ABBOTT DEFENDANTS

72. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

73. Abbott Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

74. Abbott Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

75. Abbott Defendants, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's milk-based Products.

76. Defendants breached the duty owed to Plaintiffs and acted negligently in their actions, including, but not limited to, the following:

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury, including death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;
- c. Failing to collect data to determine if its products were safe for preterm infants;
- d. Failing to collect data to determine when and how its products could be used safely;

- e. Failing to utilize the significant peer reviewed research to develop instructions;
- g. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC, serious bodily injury, including death;
- f. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC, serious bodily injury, including death;
- h. Failing to stop or deter its products from being fed to extremely preterm infants like JMR;
- g. Failing to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;
- i. Failing to continuously and vigorously study its Cow's milk-based Products in order to avoid NEC, serious bodily injury, including death in premature infants;
- h. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
- j. Failing to adopt an adequate or sufficient quality control program; and/or
- m. Failing to inspect or test their products with sufficient care.

77. Abbott Defendants knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, like JMR.

78. Abbott Defendants knew or should have known that the use of its Cow's milk-based Products with preterm infants was unreasonably dangerous in that its Cow's milk-based Products significantly increased the risk of NEC, serious bodily injury, including death.

79. Furthermore, scientific data and well researched studies have concluded

that the Cow's milk-based Products of the Abbott Defendants carried unreasonable risks of NEC, serious bodily injury, including death, which far outweighed the products' benefits for extremely premature infants like JMR.

80. As a direct and proximate result of the negligence of Abbott Defendants, JMR suffered serious bodily injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories, Inc. and Abbot Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: FAILURE TO WARN AS TO ABBOTT DEFENDANTS

81. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

82. Abbott Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's milk-based Products with preterm infants, specifically including but not limited to the risk of NEC, serious bodily injury, including death.

83. Abbott Defendants, as the manufacturer and/or seller of Cow's milk-based Products, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's milk-based Products, as the magnitude of the risk involved is using Abbott Defendants' Cow's milk-based Products with

preterm infants is significant and involves the real danger of serious bodily injury.

84. Abbott Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers in its Cow's milk-based Products.

85. Abbott Defendants owed a duty to provide warnings and instructions on its Cow's milk-based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's milk-based Products with preterm infants, specifically including but not limited to the risk of NEC, serious bodily injury, including death.

86. Rather than provide adequate warnings, Abbott Defendants developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's milk-based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

87. In addition, and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's milk-based Products with preterm infants, they would have not used

such a dangerous product.

88. Abbott Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

89. Abbott Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infant NEC, serious bodily injury, including death.

90. Abbott Defendants, through its knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's milk-based Products with preterm infants could cause severe injury, including but not limited to NEC, serious bodily injury, including death.

91. Abbott Defendants breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's milk-based Products, including but not limited to the following acts:

- a. Providing **no warnings** regarding the risk of NEC, serious bodily injury, including death;
- b. Providing inadequate labeling that failed to warn of the risks of use of Cow's milk-based Products with preterm infants, including but not limited to NEC;
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC, serious bodily injury, including death;

- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendants' Cow's milk-based Products;
- e. Failed to provide instructions to consumers and health care providers that the Defendants' products carried a significant risk that its Cow's milk-based Products could cause their baby to develop NEC, serious bodily injury, including death;
- f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's milk-based Products significantly increasing the risk of NEC, serious bodily injury, including death and fail to provide any details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that its Cow's milk-based Products are known to significantly increase the risk of NEC, serious bodily injury, including death when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked its Cow's milk-based Products to NEC, serious bodily injury, including death in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;
- j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's milk-based Products
- k. Failed to send out "Dear Dr." letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- l. Failed to advise physicians and healthcare providers that Cow's milk-based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

- m. Failed to contain sufficient instructions and warnings on the Cow's milk-based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's milk-based Products and preterm infants.

92. As a direct and proximate result of Abbott Defendants' failure to warn, JMR suffered serious bodily injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories, Inc., and Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT IV: STRICT LIABILITY AS TO MEAD DEFENDANTS DESIGN

93. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

94. At all times material to this action, Mead Defendants were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's milk-based Products, which are defectively designed and/or unreasonably dangerous to consumers, including JMR.

95. Mead Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

96. At all times material to this action, the Cow's milk-based Products manufactured, distributed and/or sold by Mead Defendants, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

97. Mead Defendants specifically marketed and created its Cow's milk-based Products for use as nutrition and nutritional supplements for preterm infants, like JMR.

98. Mead Defendants' Cow's milk-based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

99. Prior to August 2012, Mead Defendants were aware or should have been aware that its Cow's milk-based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

100. Mead Defendants knew or should have known that the use of its Cow's milk-based Products with preterm infants was unreasonably dangerous in that its Cow's milk-based Products significantly increased the risk of NEC, other serious injuries, including death.

101. Furthermore, scientific data and well-researched studies have concluded that the Cow's milk-based Products of the Defendants carried unreasonable risks of NEC including death and later developmental injuries, which far outweighed the products' benefits for preterm infants like JMR.

102. Despite the foregoing, the Mead Defendants continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

103. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

- a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's milk-based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC, serious injuries, including death;
- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as JMR to risks of serious bodily injury, including death;
- c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;
- d. Mead Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;
- e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;
- f. Mead Defendants failed to adopt an adequate or sufficient quality control program; and/or
- g. Mead Defendants failed to inspect or test their products with sufficient care.

104. As a direct and proximate cause of the Cow's milk-based Products' unreasonable dangerous condition, JMR suffered serious bodily injury, which resulted in his serious injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT V: NEGLIGENCE AS TO MEAD DEFENDANTS

105. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

106. Mead Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

107. Mead Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

108. Mead Defendants, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's milk-based Products.

109. Mead Defendants breached the duty owed to Plaintiffs and acted negligently in their actions, including, but not limited to, the following:

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury, including death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

- c. Failing to collect data to determine if its products were safe for preterm infants;
- d. Failing to collect data to determine when and how its products could be used safely;
- e. Failing to utilize the significant peer reviewed research to develop instructions;
- g. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC, serious bodily injury, including death;
- f. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC, serious bodily injury, including death;
- h. Failing to stop or deter its products from being fed to extremely preterm infants like JMR;
- g. Failing to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;
- i. Failing to continuously and vigorously study its Cow's milk-based Products in order to avoid NEC, serious bodily injury, including death in premature infants;
- h. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
- j. Failing to adopt an adequate or sufficient quality control program; and/or
- m. Failing to inspect or test their products with sufficient care.

110. Mead Defendants knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, like JMR.

111. Mead Defendants knew or should have known that the use of its Cow's milk-based Products with preterm infants was unreasonably dangerous in that its

Cow's milk-based Products significantly increased the risk of NEC, serious bodily injury, including death.

112. Furthermore, scientific data and well researched studies have concluded that the Cow's milk-based Products of the Mead Defendants carried unreasonable risks of NEC, serious bodily injury, including death, which far outweighed the products' benefits for extremely premature infants like JMR.

113. As a direct and proximate result of the negligence of Mead Defendants, JMR suffered serious bodily injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VI: FAILURE TO WARN AS TO MEAD DEFENDANTS

114. Plaintiffs incorporate by reference and re-allege paragraphs as if fully set forth herein.

115. Mead Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's milk-based Products with preterm infants, specifically including but not limited to the risk of NEC, serious bodily injury, including death.

116. Mead Defendants, as the manufacturer and/or seller of Cow's milk-

based Products, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's milk-based Products, as the magnitude of the risk involved in using Mead Defendants' Cow's milk-based Products with preterm infants is significant and involves the real danger of serious bodily injury.

117. Mead Defendants, as the manufacturer and/or seller of Cow's milk-based Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers in its Cow's milk-based Products.

118. Mead Defendants owed a duty to provide warnings and instructions on its Cow's milk-based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's milk-based Products with preterm infants, specifically including but not limited to the risk of NEC, serious bodily injury, including death.

119. Rather than provide adequate warnings, Mead Defendants developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's milk-based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions

and/or warnings from the end user.

120. In addition, and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's milk-based Products with preterm infants, they would have not used such a dangerous product.

121. Mead Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

122. Mead Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infant NEC, serious bodily injury, including death.

123. Mead Defendants, through its knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's milk-based Products with preterm infants could cause severe injury, including but not limited to NEC, serious bodily injury, including death.

124. Mead Defendants breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's milk-based Products, including but not limited to the following acts:

- a. Providing **no warnings** regarding the risk of NEC, serious bodily injury, including death;
- b. Providing inadequate labeling that failed to warn of the

risks of use of Cow's milk-based Products with preterm infants, including but not limited to NEC;

- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC, serious bodily injury, including death;
- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Mead Defendants' Cow's milk-based Products;
- e. Failed to provide instructions to consumers and health care providers that the Mead Defendants' products carried a significant risk that its Cow's milk-based Products could cause their baby to develop NEC, serious bodily injury, including death;
- f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of the Cow's milk-based Products significantly increasing the risk of NEC, serious bodily injury, including death and fail to provide any details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that its Cow's milk-based Products are known to significantly increase the risk of NEC, serious bodily injury, including death when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked its Cow's milk-based Products to NEC, serious bodily injury, including death in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;
- j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's milk-based Products
- k. Failed to send out "Dear Dr." letters warning of the risks of

NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

- l. Failed to advise physicians and healthcare providers that Cow's milk-based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or
- m. Failed to contain sufficient instructions and warnings on the Cow's milk-based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's milk-based Products and preterm infants.

125. As a direct and proximate result of Mead Defendants' failure to warn, JMR suffered serious bodily injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendants Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

DEMAND FOR JURY TRIAL

Plaintiffs hereby requests a trial by jury on all issues triable by jury.

Date: December 9, 2022

Respectfully submitted,

SIMON GREENSTONE PANATIER, P.C.

/s/ Shreedhar R. Patel

Shreedhar R. Patel, TX Bar No. 24074864
1201 Elm Street, Suite 3400
Dallas, TX 75270
Tele.: (214) 276-7680
Fax: (214) 276-7699
E-mail: spatel@sgptrial.com

Attorney for Plaintiffs